

AB-334U

RECEIVED
CENTRAL FAX CENTER

10/642,851

JUL 06 2006

IN THE SPECIFICATION:

Please amend the following paragraphs as indicated:

[0012] The present systems and methods address invention addresses the above and other needs by providing systems and methods for implanting a medical device such as a lead into the brain and avoids lead displacement once the "best" target site in the brain is located and components such as a recording microelectrode and a cannula are removed from the stereotactic frame.

[0013] The present systems and methods include invention includes a slit cannula, an elongated medical device within the lumen of the slit cannula, and a lock for securing the elongated medical device through the slit in the cannula. The lock is fastened to a reference platform, which reference platform is attached to a stereotactic frame.

[0014] In one aspect of the present systems and methods invention, the elongated medical device is a lead or catheter with an offset portion. The offset portion may be a tab, knob, bulge, parallel lead, or any other structure along the side of the lead to which the lock may attach. The offset portion may also be a paddle electrode connector or other electrode connector of the lead. The electrode connector is capable of forming an electrical connection with an operating room cable connected to an external trial stimulator.

AB-334U

10/642,851

[0015] In another aspect of the present systems and methods invention, the elongated medical device has a lumen through its axis, and the lumen preferably does not continue through the offset portion. The lumen of the lead may be dimensioned to permit a microelectrode to be inserted into the lead lumen.

[0016] Conventionally, when a cannula enveloping a lead is removed from a stereotactic frame, the cannula is pulled upward, away from the brain, as it slides like a sleeve off of the lead. Before the distal tip of the cannula exits the skull, the proximal tip of the cannula has covered the proximal end of the lead. Thus, as the proximal length of the lead is cloaked by the cannula and the distal length of the lead is cloaked by the skull, dura mater, and brain, no portion of the lead is visible to the surgeon. Yet, in order to insure that the lead does not move during removal of the cannula and other structures, e.g., the recording microelectrode, it is critical that at least a portion of the lead be seen by the surgeon at all times, and if possible, locked into place. The present systems and methods avoid invention avoids lead displacement by permitting a surgeon to view and lock the lead into place at all times during the removal of a cannula and other structures such as the recording microelectrode.

[0017] The present systems and methods allow invention allows a surgeon to remove a recording microelectrode before or after a cannula is removed. The present systems and methods invention also allow allows a surgeon to place a non-isodiametric lead within a cannula lumen. Further, the present systems and methods prevent invention prevents fluid ingress into the connector end of a lead. Further still, the present systems and methods allow invention allows a

AB-334U

10/642,851

surgeon to deliver continuous stimulation and receive continuous recording signals through the lead during removal of the surgical insertion tools (i.e., the cannula, recording microelectrode, and other devices) in order to continuously monitor any potential changes in stimulation efficacy of the lead during removal of the insertion tools.

[0018] The above and other aspects of the present systems and methods invention will be more apparent from the following more particular description thereof, presented in conjunction with the following drawings wherein:

[0019] FIG. 1A shows a front view of an offset lead of the present systems and methods invention;

[0020] FIG. 1B shows a front view of a DBS lead system of the present systems and methods invention;

[0027] The following description includes the best mode presently contemplated for carrying out the present systems and methods invention. This description is not to be taken in a limiting sense, but is made merely for the purpose of describing the general principles of the present systems and methods invention. The scope of the invention should be determined with reference to the claims.

AB-334U

10/642,851

[0028] The present invention includes systems and methods described herein that allow for visualization and locking of a deep brain stimulation (DBS) lead, or other elongated medical structure, during a surgical tool removal process of a DBS procedure, hence eliminating the risk of lead movement. Visualization and locking of the lead during the surgical removal process can be accomplished using a unique lead system.

[0030] Because the lead is anchored by means of a lead lock to a permanent reference point, a surgeon is able to remove both the slit cannula and the recording microelectrode without disturbing the location of the lead within the brain. Even a slight movement of a lead from its target site within the brain of a patient can dramatically decrease the therapeutic effect of the lead for the patient. Thus, the present systems and methods invention locks the lead into place once the lead has been placed in a location of maximum therapeutic effect for the patient.

[0032] FIG. 1B shows a front view of an embodiment of the DBS lead system of the present systems and methods invention. The DBS lead system of FIG. 1B includes offset lead 100, which can also be a catheter or other similar insertable medical device; slit cannula 110; and lead lock 120. FIG. 1B also shows stereotactic frame 130, which holds the components of the DBS lead system during a DBS procedure; a stylet and/or recording microelectrode 140 inserted within the lumen of lead 100; and a skull 150, dura mater 160, and brain 170 of a patient. The DBS lead system is fully engaged with stereotactic frame 130, and the distal ends of both offset lead 100 and slit cannula 110 are inserted into brain 170.

AB-334U

10/642,851

[0034] FIGS. 1B through 2D show lead 100 locked to lead lock 120 at an elevated point above the skull of a patient. However, the present systems and methods include invention includes locking lead 100 to lead lock 120 at locations along lead 100 that are closer to the skull than shown in FIGS. 1B through 2D. In some examples Preferably, lead 100 is locked to lead lock 120 just above the site of entry into the skull. Lead 100, or another elongated medical device locked by lead lock 120, may be made of malleable or elastic material. Therefore, lead 100 may move slightly when other devices in contact with lead 100 are moved. Lead 100 may move despite the fact that it is locked into place by lead lock 120. Locking the lead 100 at or just above the site of entry into the skull minimizes unwanted movement of lead 100 during movement of other structures in contact with lead 100. Movement is minimized because lead 100 is stabilized by lead lock 120, the skull, and brain tissue and because the distance between the point at which lead 100 is locked and the target site in the brain is minimized.

[0043] While the systems and methods invention herein disclosed have has been described by means of specific embodiments and applications thereof, numerous modifications and variations could be made thereto by those skilled in the art without departing from the scope of the invention set forth in the claims.